



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,872	09/30/2003	Galina Fomovskaia	56075-PCT-CIP-C (45858)	7999
21874 7590 01/24/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER WILDER, CYNTHIA B	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/676,872	FOMOVSKAIA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4-8, 12-16 and 37-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-8, 12-16 and 37-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/2007 has been entered. Claims 1-3, 9-11, 15, 17-36 have been canceled. Claims 4, 12, 16, 46 and 47 have been amended. Claim 53 has been added. All of the arguments have been thoroughly reviewed and considered, but are deemed moot in view of the new ground(s) of rejections necessitated by Applicant's amendment of the claims.

### ***Previous Rejections***

2. The prior art rejection under 35 USC 102(b) as being anticipated by Bloch et al is withdrawn in view of Applicant's amendment and arguments. The claim rejection under 35 USC 102 (b) as being anticipated by Burgoyne et al is withdrawn in view of Applicant's amendment. The prior art rejection under 35 USC 103(a) as being unpatentable over Burgoyne et al in view of Ahern is withdrawn in view of Applicant's amendment. The prior art rejection under 35 USC 103(a) as being unpatentable over Burgoyne in view of Ahern in view of Bloch et al and Anderson is withdrawn in view of Applicant's amendment.

***Declaration***

3. The declaration under 37 CFR 1.132 filed 10/29/2007 is sufficient to overcome the rejection of 4-8, 12-14, 16 and 37-52 as previously presented. However, the declaration under 37 CFR 1.132 is insufficient to overcome the new ground(s) of rejections necessitated by Applicant's amendment of the claims. The declaration does not address the new grounds of rejections as presented below.

***New Ground(s) of Rejections***

***THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:***

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 4-8, 12-17 and 37-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne et al in view of Bloch et al (citation made of record in the prior Office action). Regarding claims 4, 5, 12, 16, and 46, Burgoyne teaches a dry substrate and a blood card (sheet or paper) consisting of a solid matrix which comprises a cellulose-based paper (nitrocellulose) (col. 2, lines 21-25) or a chemically modified cellulose (col. 2, lines 21-23); a coating functionally sorbed to the solid matrix, wherein the coating comprises a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration sufficient to induce cellular lysis (col. 2, lines 59-64 and col. 4, lines 5-14, 35-40) and an indicator which is an external substance, which is maintained on the solid matrix, wherein the indicator is a color indicator (ink stamp or pencil marking) (col. 5, lines 8-15) and an integrity maintenance means (col. 3, lines 1-6).

Burgoyne does not teach wherein the dry substrate or blood card is packaged in the form of a kit or wherein the external substance of the indicator generates a signal in an assay.

Bloch et al teaches a solid matrix, wherein the solid matrix comprises a coating functionally associated with the solid matrix (col. 17, lines 53-68), wherein the matrix comprises nitrocellulose or nylon (col. 17, lines 63-64); a coating functionally associated with the solid matrix, wherein the coating comprising an anionic detergent (col. 14, lines 8-14 and 56-64) and an indicator which is maintained on the solid matrix, and wherein said indicator comprises an external substance which generates a signal in an assay

(col. 11, lines 28-30; col. 15, lines 26-32, 56-59; col. 16, lines 41-56; col. 23, lines 39-47 and col. 31, lines 9-18). Bloch et al teaches the components in the form of a kit.

Bloch et al recognizes the need in the art for solid matrix having a visual indicator adsorbed thereto. Bloch et al teaches that there is a growing use in clinical diagnostics of "rapid" immunodiagnostic kits in which immune reactions are performed and detected in or above filtration membrane (col. 5, lines 39-42). Bloch provides a means for improving this problem by providing indicators useful for visualizing biological materials (col. 5, lines 47-48), which includes nucleic acids (col. 10, lines 62-68).

Since Bloch et al recognizes a need for immunodiagnostic kits that are capable of rapidly detecting a target molecule of interest, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to improve the dry solid matrix of Burgoyne by including an indicator means, wherein the indicator is a color or fluorescent indicator, for the predictable result of enabling a rapid identification of a target biological molecule.

Additionally, since the addition of an indicator to the dry solid matrix of Burgoyne would not effect the function of the dry solid matrix, and could be easily combined with the dry solid matrix as taught by Bloch et al, it would be obvious to one having ordinary skill in the art to utilize an indicator capable of generating a signal in an assay for the predictable results of detecting a target molecule of interest in a rapid, simple and efficient manner without the need for numerous reagents and materials. Such material in a kit would provide added convenience to the practitioner.

Regarding claim 6, Burgoyne teaches wherein said substrate is a sheet (filter) or card (col. 2, lines 21-23 and col. 4, lines 61-65). Bloch et al also teaches wherein the substrate is in the shape of a sheet or ball (col. 8, lines 9-10; col. 12, lines 21-22 and col. 17, lines 54-58).

Regarding claim 7, Burgoyne teaches wherein the substrate further includes an integrity maintenance means (col. 3, lines 1-6). Bloch et al also supports this limitation (col. 35, line 68 to col. 36, line 1).

Regarding claim 8, Burgoyne teaches wherein said substrate is a sheet (filter) and said integrity maintenance means is a plastic encasing (col. 3, lines 1-6).

Regarding claim 13, Burgoyne teaches wherein the coated matrix is in a shape from the group consisting essentially of a sheet (col. 2, lines 24-25). Bloch also supports this limitation (col. 35, line 68 to col. 36, line 1). Bloch et al supports this limitation (col. 8, lines 9-10; col. 12, lines 21-22 and col. 17, lines 54-58).

Regarding claim 14, Burgoyne teaches wherein said coated matrix is in a shape selected from the group consisting essentially of a plastic bag (col. 5, line 52). Bloch supports this limitation (col. 35, line 68 to col. 36, line 1).

Regarding claims 37 and 41, Burgoyne teaches wherein the anionic surfactant or detergent is SDS (col. 3, lines 24-25).

Regarding claims 38 and 42, Burgoyne teaches wherein the weak base comprises a Tris and the chelating agent comprises EDTA (Example 1).

Regarding claims 39 and 43, Burgoyne teaches wherein the anionic surfactant or SDS at a concentration of from about 5% (col. 4, line 37).

Regarding claims 40 and 44, Burgoyne teaches wherein the coating further comprises a free radical trap, uric acid or a urate salt (col. 3, line 26 and 36-45).

Regarding claim 45, Bloch teaches wherein the indicator means is a color or fluorescent indicator (col. 31, lines 9-18; col. 23, lines 39-47 and col. 11, lines 28-30).

Regarding claim 47, Bloch et al teach wherein the dry substrate comprises an indicator comprising an enzyme linked immunosorbant assay (ELISA or EIA) (col. 12, lines 28-47; and col. 17).

Regarding claim 48, Burgoyne teaches wherein the anionic surfactant or detergent is SDS (col. 3, lines 24-25).

Regarding claim 49, Burgoyne teaches wherein the weak base comprises a Tris and the chelating agent comprises EDTA (Example 1).

Regarding claim 50, Burgoyne teaches wherein the anionic surfactant or SDS at a concentration of from about 5% (col. 4, line 37).

Regarding claim 51, Burgoyne teaches wherein the coating further comprises a free radical trap uric acid or a urate salt (col. 3, line 26 and 36-45).

Regarding claim 52, Bloch et al teach wherein the target is a biological molecule which may encompass a nucleic acid of interest and further teaches wherein the indicator comprises an ELISA using antibodies to the target (see col. 12, lines 42-65 and col. 15, line 60 to col. 16, line 32 and col. 19, line 66 to col. 20, line 1).

Regarding claim 53, Bloch et al teach wherein the indicator comprises an enzyme-linked immunosorbant assay (ELISA) (col. 12, lines 42-65; col. 15, line 60 to col. 16, line 32 and col. 19, line 66 to col. 20, line 1).

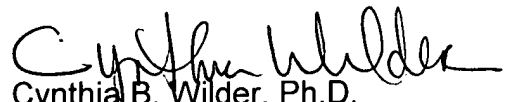


**Conclusion**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Cynthia B. Wilder, Ph.D.  
Patent Examiner  
Art Unit 1637

01/17/2008